

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

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AUTHORITY: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

SOURCE: 66 FR 37814, July 19, 2001, unless otherwise noted.

Subpart A—General Provisions

§ 174.1 Scope and purpose.

The characteristics of plant-incorporated protectants such as their production and use in plants, their biological properties, and their ability to spread and increase in quantity in the environment distinguish them from traditional chemical pesticides. Therefore, plant-incorporated protectants are subject to some different regulatory requirements and procedures than traditional chemical pesticides. This part sets forth regulatory requirements, criteria, and procedures applicable to plant-incorporated protectants under FIFRA and FFDCA. When applied to plant-incorporated protectants, the definitions and regulations in this part supersede the regulations found in parts 150 through 180 of this chapter to the extent that the regulations conflict. Unless otherwise superseded by this part, the regulations in parts 150 through 180 of this chapter apply to plant-incorporated protectants.

§ 174.3 Definitions.

Terms used in this part have the same meaning as in FIFRA. In addition, the following terms have the meaning set forth in this section.

Active ingredient means a pesticidal substance that is intended to be pro-

duced and used in a living plant, or in the produce thereof, and the genetic material necessary for the production of such a pesticidal substance.

Administrator means the Administrator of the United States Environmental Protection Agency or his/her delegate.

Bridging crosses between plants means the utilization of an intermediate plant in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

Cell fusion means the fusion *in vitro* of two or more cells or protoplasts.

Conventional breeding of plants means the creation of progeny through either: The union of gametes, *i.e.*, syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include use of any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.

EPA means the United States Environmental Protection Agency.

Exudate means a substance gradually discharged or secreted across intact cellular membranes or cell walls and present in the intercellular spaces or on the exterior surfaces of the plant.

FFDCA means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 *et seq.*).

Food includes articles used for food or drink by humans or other animals.

Food plant means a plant which either in part or *in toto*, is used as food.

Genetic material necessary for the production means both: Genetic material that encodes a substance or leads to

the production of a substance; and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

Genome means the sum of the heritable genetic material in the plant, including genetic material in the nucleus and organelles.

In a living plant means inside the living plant, on the surface of the living plant, or as an exudate from the living plant.

Inert ingredient, means any substance, such as a selectable marker, other than the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient, and includes the genetic material necessary for the production of the substance, provided that genetic material is intentionally introduced into a living plant in addition to the active ingredient.

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include, but are not limited to, linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Nucleic acids means ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil; polymers of the deoxyribose-5'-monophosphates of thymine, cytosine, guanine, and adenine linked by successive 3'-5' phosphodiester bonds (also known as deoxyribonucleic acid); and polymers of the ribose-5'-monophosphates of uracil, cytosine, guanine, and adenine linked by successive 3'-5' phosphodiester bonds (also known as ribonucleic acid). The term does not apply to nucleic acid analogues (e.g., dideoxycytidine), or polymers containing nucleic acid analogues.

Pesticidal substance, means a substance that is intended to be produced and used in a living plant, or in the produce thereof, for a pesticidal purpose, during any part of a plant's life

cycle (e.g., in the embryo, seed, seedling, mature plant).

Plant, for plant-incorporated protectants, means an organism classified using the 5-kingdom classification system of Whittaker in the kingdom Plantae. This includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns, gymnosperms such as conifers, and angiosperms such as most major crop plants.

Plant-incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.

Produce thereof, when used with respect to plants containing plant-incorporated protectants only, means a product of a living plant containing a plant-incorporated protectant, where the pesticidal substance is intended to serve a pesticidal purpose after the product has been separated from the living plant. Examples of such products include, but are not limited to, agricultural produce, grains, and lumber. Products such as raw agricultural commodities bearing pesticide chemical residues are not "produce thereof" when the residues are not intended to serve a pesticidal purpose in the produce.

Recipient plant means the living plant in which the plant-incorporated protectant is intended to be produced and used.

Recombinant DNA means the genetic material has been manipulated *in vitro* through the use of restriction endonucleases and/or other enzymes that aid in modifying genetic material, and subsequently introduced into the genome of the plant.

Regulatory region means genetic material that controls the expression of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include, but are not limited to, promoters, enhancers, and terminators.

Sexually compatible, when referring to plants, means a viable zygote is formed

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only through the union of two gametes through conventional breeding.

Source means the donor of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance.

Vegetative reproduction means either:

(1) In seed plants, reproduction by apomixis, or

(2) In other plants, reproduction by fragmentation, or division of the somatic body.

Wide crosses means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures.

§ 174.9 Confidential business information claims for plant-incorporated protectant submissions.

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information (CBI), a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant. (See part 2, subpart B of this chapter.) To assert such a claim, the submitter must comply with all of the following procedures:

(a) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

(b) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the points listed in § 2.204(e)(4) of this chapter in the substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing infor-

mation claimed as CBI that are not accompanied by substantiation, and will suspend any applicable review of such submissions until the required substantiation is provided.

Subpart B—Exemptions

§ 174.21 General qualifications for exemptions.

A plant-incorporated protectant is exempt from the requirements of FIFRA, other than the requirements of § 174.71, if it meets all of the following criteria:

(a) The plant-incorporated protectant meets the criteria listed in at least one of the sections in §§ 174.25 through 174.50.

(b) When the plant-incorporated protectant is intended to be produced and used in a crop used as food, the residues of the plant-incorporated protectant are either exempted from the requirement of a tolerance under FFDCA (as amended, 21 U.S.C. 321 *et seq.*) as codified at §§ 174.507 through 174.508, or no tolerance would otherwise be required for the plant-incorporated protectant.

(c) Any inert ingredient that is part of the plant-incorporated protectant is on the list codified at § 174.705. Plant-incorporated protectants that are not exempt from the requirements of FIFRA under this subpart are subject to all the requirements of FIFRA.

[66 FR 37814, July 19, 2001, as amended at 72 FR 20434, Apr. 25, 2007]

§ 174.25 Plant-incorporated protectant from sexually compatible plant.

A plant-incorporated protectant is exempt if all of the following conditions are met:

(a) The genetic material that encodes the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient plant.

Subpart C—Registration Procedures and Requirements [Reserved]

**Subpart D—Monitoring and
Recordkeeping**

**§ 174.71 Submission of information re-
garding adverse effects.**

(a) Any person who produces, for sale or distribution, a plant-incorporated protectant exempt under subpart B of this part, who obtains any information regarding adverse effects on human health or the environment alleged to have been caused by the plant-incorporated protectant must submit such information to EPA. This requirement does not apply to any person who does not produce a plant-incorporated protectant exempt under subpart B of this part. This may include, for example, researchers performing field experiments, breeders making crosses among plant varieties with the goal of developing new plant varieties, or a person who only sells propagative materials (e.g., seed) to farmers without producing the propagative materials themselves. EPA must receive the report within 30 calendar days of the date the producer first possesses or knows of the information.

(b) Adverse effects on human health or the environment for purposes of plant-incorporated protectant means at a minimum information about incidents affecting humans or other nontarget organisms where both:

(1) The producer is aware, or has been informed, that a person or nontarget organism allegedly suffered a toxic or adverse effect due to exposure to (e.g., ingestion of) a plant-incorporated protectant.

(2) The producer has or could reasonably obtain information concerning where the incident occurred.

(c) All of the following information, if available, must be included in a report.

(1) Name of reporter, address, and telephone number.

(2) Name, address, and telephone of contact person (if different than reporter).

(3) Description of incident.

(4) Date producer became aware of incident.

(5) Date of incident.

(6) Location of incident.

(d) Reports and questions should be submitted to the Office of Pesticide

Programs' Document Processing Desk at the appropriate address as set forth in 40 CFR 150.17(a) or (b).

[66 FR 37814, July 19, 2001, as amended at 71 FR 35546, June 21, 2006]

Subparts E–F [Reserved]

Subpart G—Labeling [Reserved]

**Subpart H—Data Requirements
[Reserved]**

Subpart I [Reserved]

**Subpart J—Good Laboratory
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**Subpart K—Export Requirements
[Reserved]**

Subparts L–T [Reserved]

**Subpart U—Experimental Use
Permits [Reserved]**

Subpart V [Reserved]

**Subpart W—Tolerances and
Tolerance Exemptions**

§ 174.500 Scope and purpose.

This subpart lists the tolerances and exemptions from the requirement of a tolerance for residues of plant-incorporated protectants in or on food commodities.

[72 FR 20434, Apr. 25, 2007]

**§ 174.501 *Bacillus thuringiensis*
Vip3Aa19 protein in cotton; tem-
porary exemption from the require-
ment of a tolerance.**

Residues of *Bacillus thuringiensis* Vip3Aa19 protein in cotton are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities of cotton; vegetative-insecticidal protein in cotton, undelinted seed, cotton, oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton, gin byproducts. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this section when

treated in accordance with the provisions of the experimental use permit 67979-EUP-7, which is being extended in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked May 1, 2009; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the temporary tolerance exemption is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[72 FR 68748, Dec. 6, 2007]

§ 174.502 *Bacillus thuringiensis* Cry1A.105 protein in corn; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1A.105 protein in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop. This temporary exemption from the requirement of a tolerance will permit the use of the food commodities in this paragraph when treated in accordance with the provisions of the experimental use permit 524-EUP-97 which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked June 30, 2009; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[72 FR 20434, Apr. 25, 2007]

§ 174.503 *Bacillus thuringiensis* Cry2Ab2 protein in corn; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry2Ab2 protein in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet;

and corn, pop. This temporary exemption from the requirement of a tolerance will permit the use of the food commodities in this paragraph when treated in accordance with the provisions of the experimental use permit 524-EUP-97 which is being issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is revoked June 30, 2009; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the tolerance is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[72 FR 20434, Apr. 25, 2007]

§ 174.504 *Bacillus thuringiensis* Cry1F protein in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1F protein in cotton are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in food and feed commodities of cotton.

[72 FR 20434, Apr. 25, 2007]

§ 174.505 *Bacillus thuringiensis* modified Cry3A protein (mCry3A) in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* modified Cry3A protein (mCry3A) in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectant in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20434, Apr. 25, 2007]

§ 174.506 *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry34Ab1 and Cry35Ab1 proteins in corn are exempted from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20434, Apr. 25, 2007]

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§ 174.507 Nucleic acids that are part of a plant-incorporated protectant; exemption from the requirement of a tolerance.

Residues of nucleic acids that are part of a plant-incorporated protectant are exempt from the requirement of a tolerance.

[66 FR 37830, July 19, 2001. Redesignated at 72 FR 20434, April 25, 2007]

§ 174.508 Pesticidal substance from sexually compatible plant; exemption from the requirement of a tolerance.

Residues of a pesticidal substance that is part of a plant-incorporated protectant from a sexually compatible plant are exempt from the requirement of a tolerance if all the following conditions are met:

(a) The genetic material that encodes for the pesticidal substance or leads to the production of the pesticidal substance is from a plant that is sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the pesticidal substance are not present in food from the plant at levels that are injurious or deleterious to human health.

[66 FR 37854, July 19, 2001. Redesignated at 72 FR 20434, April 25, 2007]

§ 174.509 *Bacillus thuringiensis* Cry3A protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry3A protein are exempted from the requirement of a tolerance when used as a plant-incorporated protectant in potatoes.

[72 FR 20435, Apr. 25, 2007]

§ 174.510 *Bacillus thuringiensis* Cry1Ac protein in all plants; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1Ac protein in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectants in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.511 *Bacillus thuringiensis* Cry1Ab protein in all plants; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1Ab protein in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectants in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.512 Coat Protein of Potato Virus Y; exemption from the requirement of a tolerance.

Residues of Coat Protein of Potato Virus Y are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.513 Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene); exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the plant-incorporated protectant Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene) in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.514 Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic Virus; exemption from the requirement for a tolerance.

Residues of Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic Virus are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.515 Coat Protein of Papaya Ringspot Virus; exemption from the requirement of a tolerance.

Residues of Coat Protein of Papaya Ringspot Virus are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

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§ 174.516 Coat protein of cucumber mosaic virus; exemption from the requirement of a tolerance.

Residues of Coat Protein of Cucumber Mosaic Virus are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in or on all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.517 *Bacillus thuringiensis* Cry9C protein in corn; exemption from the requirement of a tolerance.

The plant-incorporated protectant *Bacillus thuringiensis* Cry9C protein in corn is exempted from the requirement of a tolerance for residues, only in corn used for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.

[72 FR 20435, Apr. 25, 2007]

§ 174.518 *Bacillus thuringiensis* Cry3Bb1 protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry3Bb1 protein in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20435, Apr. 25, 2007]

§ 174.519 *Bacillus thuringiensis* Cry2Ab2 protein in cotton; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry2Ab2 protein in cotton is exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities, cotton seed, cotton oil, cotton meal, cotton hay, cotton hulls, cotton forage, and cotton gin byproducts.

[72 FR 20435, Apr. 25, 2007]

§ 174.520 *Bacillus thuringiensis* Cry1F protein in corn; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Cry1F protein in corn are exempt from the requirement of a tolerance when used as plant-incorporated protectants in the food and feed commodities of

corn; corn, field; corn, sweet; and corn, pop.

[72 FR 20435, Apr. 25, 2007]

§ 174.521 Neomycin phosphotransferase II; exemption from the requirement of a tolerance.

Residues of the neomycin phosphotransferase II (NPTII) enzyme are exempted from the requirement of a tolerance in all food commodities when used as a plant-incorporated protectant inert ingredient.

[72 FR 20435, Apr. 25, 2007]

§ 174.522 Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance.

Residues of the Phosphinothricin Acetyltransferase (PAT) enzyme are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance.

Residues of the CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase enzyme in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.524 Glyphosate Oxidoreductase GOX or GOXv247 in all plants; exemption from the requirement of a tolerance.

Residues of the Glyphosate Oxidoreductase GOX or GOXv247 enzyme in all plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

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§ 174.525 *E. coli* B-D-glucuronidase enzyme as a plant-incorporated protectant inert ingredient; exemption from the requirement of a tolerance.

Residues of *E. coli* B-D-glucuronidase enzyme are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.526 Hygromycin B phosphotransferase (APH4) marker protein in all plants; exemption from the requirement of a tolerance.

Residues of the Hygromycin B phosphotransferase (APH4) enzyme in all plants are exempt from the requirement of a tolerance when used as a plant-incorporated protectant inert ingredient in cotton.

[72 FR 20435, Apr. 25, 2007]

§ 174.527 Phosphomannose isomerase in all plants; exemption from the requirement of a tolerance.

Residues of the phosphomannose isomerase (PMI) enzyme in plants are exempt from the requirement of a tolerance when used as plant-incorporated protectant inert ingredients in all food commodities.

[72 FR 20435, Apr. 25, 2007]

§ 174.528 *Bacillus thuringiensis* Vip3Aa20 protein in corn; temporary exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vip3Aa20 protein in corn are temporarily exempt from the requirement of a tolerance when used as a plant-incorporated protectant in the food and feed commodities; corn, field; corn, sweet; and corn, pop. This temporary exemption from the requirement of tolerance will permit the use of the food commodities in this section when treated in accordance with the provisions of the experimental use permit 67979-EUP-6, which is being amended and extended in accordance with the provisions of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136). This temporary exemption from the requirement of a tolerance expires and is re-

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voked October 31, 2009; however, if the experimental use permit is revoked, or if any experience with or scientific data on this pesticide indicate that the temporary tolerance exemption is not safe, this temporary exemption from the requirement of a tolerance may be revoked at any time.

[72 FR 68529, Dec. 5, 2007]

Subpart X—List of Approved Inert Ingredients

§ 174.700 Scope and purpose.

This subpart lists the inert ingredients that have been exempted from FIFRA and FFDCA section 408 requirements and may be used in a plant-incorporated protectant listed in subpart B of this part.

[66 FR 37814, July 19, 2001. Redesignated at 72 FR 20434, Apr. 25, 2007]

§ 174.705 Inert ingredients from sexually compatible plant.

An inert ingredient, and residues of the inert ingredient, are exempt if all of the following conditions are met:

(a) The genetic material that encodes the inert ingredient or leads to the production of the inert ingredient is derived from a plant sexually compatible with the recipient food plant.

(b) The genetic material has never been derived from a source that is not sexually compatible with the recipient food plant.

(c) The residues of the inert ingredient are not present in food from the plant at levels that are injurious or deleterious to human health.

[66 FR 37814, July 19, 2001. Redesignated at 72 FR 20434, Apr. 25, 2007]

Subparts Y–Z [Reserved]

PART 176—TIME-LIMITED TOLERANCES FOR EMERGENCY EXEMPTIONS

Sec.

176.1 Scope and applicability.

176.3 Definitions.

176.5 Establishment of a time-limited tolerance or exemption.

176.7 Information needed to establish a tolerance.

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